

Notice of Allowability

Application No.

09/856,415

Examiner

Humera N. Sheikh

Applicant(s)

TALTON ET AL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 13 June 2005.
2. ☒ The allowed claim(s) is/are 28,30-44 and 48-67.
3. ☒ The drawings filed on 18 May 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 6/20/05.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Final Rejection and Applicant's Arguments/Remarks, both filed 06/13/05 is acknowledged.

Claims 28, 30-44 and 48-67 are pending. Claim 57 has been amended via Examiner's Amendment. Claim 29 has been cancelled. Claims 28, 30-44 and 48-67 are allowed.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Neil R. Jetter on June 20, 2005.

The application has been amended as follows:

In the Claims:

In Claim 57, line 2, the phrase '*in accordance with claim 28*' has been *deleted* and *replaced with* the phrase 'comprising a plurality of coated drug particles, each of said coated drug particles having an average particle size of less than 50 μm in diameter, the surface of said

particles comprising at least a first coating layer of biodegradable and bio-compatible material, said coating layer being a continuous and non-porous layer, wherein an average thickness of said coating layer is between 1 and 500 nm, wherein said coating layer is exclusive of said drug provided by said drug particles.'

Allowable Subject Matter

Claims 28, 30-44 and 48-67 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Moro *et al.* US 5,223,244; Green *et al.* US 5,976,577; Sakon *et al.* US 5,972,388; Hanes *et al.* US 5,855,913; Bucks *et al.* US 6,277,364) does not disclose nor fairly suggest a medicament comprising coated drug particles, each of the said coated drug particles having an average particle size of less than 50 μm in diameter, the surface of said particles comprising a first coating layer of biodegradable and biocompatible material, wherein the coating layer is a continuous, non-porous layer, having an average thickness of between 1 and 500 nm, and wherein the coating layer is exclusive of said drug provided by said drug particles. In the Final Office Action filed 06/03/05, the Examiner objected to claim 29, which specifically recites that the "coating layer is exclusive of said drug provided by said drug particles" and indicated that claim 29 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have adopted the Examiner's suggestion and have incorporated the claim limitations of allowable claim 29 into independent claim 28, canceling claim 29. Additionally, Applicants

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have incorporated the allowable claim limitations of claim 29 into independent method claim 66, to place the application in condition for allowance. The instant invention provides for an improvement over prior art formulations because it allows for control of the coating layer and in particular, control of the thickness and uniformity of the coating layer and offers encapsulation that can be partial or complete. Accordingly, since the prior art fails to disclose or suggest the claimed medicament of the instant invention, the instant invention is rendered non-obvious and *patentable* over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

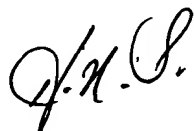
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh



Patent Examiner

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June 20, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

